ARC 7446B

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 13, "Sterile Compounding Practices," Iowa Administrative Code.

The amendments were approved at the November 19, 2008, regular meeting of the Board of Pharmacy.

The proposed amendments combine the requirements for testing and quarantine of sterile compounds into a single subrule, including rescinding a duplicative subrule, and clarify the products and criteria for quarantine and testing.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 20, 2009. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

These amendments are intended to implement Iowa Code sections 124.301, 155A.2, 155A.13, and 155A.13A.

The following amendments are proposed.

ITEM 1. Amend subrule 13.24(4) as follows:

13.24(4) *Testing and quarantine requirements.* All high-risk preparations, except those for inhalation and ophthalmic administration, that are prepared in groups of 25 or more identical single-dose containers or in multiple-dose vials for administration to multiple patients, or that are exposed longer than 12 hours at 2 to 8 degrees Celsius ~~and~~ or longer than 6 hours at warmer than 8 degrees Celsius before they are sterilized, shall be quarantined and tested to ensure that the preparations are sterile and that they do not contain excessive bacterial endotoxins before they are dispensed or administered.

ITEM 2. Rescind subrule **13.24(6)**.